1224 '99 OCT 20 A11 :25

ARROW INTERNATIONAL

2400 Bernville Road
Reading, PA 19605 USA

(610) 478-3137
FAX: (610) 478-3172

e-mail: tom_nickel@arrowintl.com
www.arrowintl.com

October 11, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

RE: Federal Register notice of October 1, 1999, Docket Number 99N-2099 – General Hospital and Personal Use Devices; classification of the Subcutaneous, Implanted, Intravascular Infusion Port and Catheter and the Percutaneous, Implanted, Long-Term Intravascular Catheter

Dear Sir or Madam:

As a manufacturer of subject infusion port we concur with your proposal to classify the device in class II (special controls).

Sincerely,

Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

c: C. Botterbusch
J. Bonasera
G. Haas

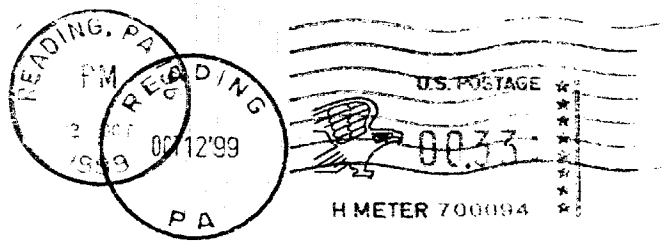
99109ltr

99N-2099

C1

ARROW
INTERNATIONAL

P.O. Box 12888
Reading, PA 19612



Dockets Management Branch (HFA-305)
Food and Drug Administration

5630 Fishers Lane, Room 1061
Rockville, MD 20857